

Cerliponase alfa (Brineura®)

Place of Service

Infusion Center
Office Administration
Outpatient Facility Administration
Hospital Administration

HCPCS: J0567 per 1 mg

Condition listed in policy (see criteria for details)

- [Late infantile neuronal ceroid lipofuscinosis type 2 \(CLN2\) disease](#)

AHFS therapeutic class: Enzymes

Mechanism of action: Hydrolytic lysosomal N-terminal tripeptidyl peptidase

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Brineura® (cerliponase alfa) must be sent for clinical review and receive authorization for both cerliponase alfa and for hospital admission prior to drug administration or claim payment.

Late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) disease

1. Diagnosis of symptomatic late infantile onset CLN2 disease, AND
2. Diagnosis by geneticist or pediatric neurologist, AND
3. Confirmed with documentation of either:
 - a. TPP1 enzyme deficiency, OR
 - b. Two pathogenic variants/mutations on separate parental alleles (i.e., in trans) in the TPP1/CLN2 gene,

AND

4. Patient is aged 3 years or older, AND
5. Patient is ambulatory

Covered Doses

Up to 300 mg ICV (intracerebroventricular) infusion every other week

Coverage Period

Indefinite

ICD-10:

E75.4

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

PHP Medi-Cal

Cerliponase alfa (Brineura®)

All requests for Brineura® (cerliponase alfa) must be sent for clinical review and receive authorization for both cerliponase alfa and for hospital admission prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 150 mg/5 mL (single-dose vials)

(6) References

- AHFS®. Available by subscription at <http://www.lexi.com>
- Brineura® (cerliponase alfa) [Prescribing information]. Novato, CA. BioMarin Pharmaceutical Inc.; 3/2020.
- Diagnosis of neuronal ceroid lipofuscinosis type 2 (CLN2 disease): Expert recommendations for early detection and laboratory diagnosis. Mol Genet Metab 2016; 119(1-2):160-7.
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Mole SE, Schulz A, Badoe E, et al. Guidelines on the diagnosis, clinical assessments, treatment and management for CLN2 disease patients. Orphanet J Rare Dis 2021; 16:185.

(7) Policy Update

Date of last review: 3Q2023

Date of next review: 3Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*